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OLC 78-2265/2 *Pro/Sec*

16 NOV 1978

MEMORANDUM FOR: Office of Medical Services/DDA
Office of Security/DDA
Chief, Policy Guidance and Legal Affairs Control/
PCS/DDO
Chief, Central Cover Staff/DDO

STAT FROM :
Assistant Legislative Counsel

SUBJECT : HEW Draft Bill Entitled "Privacy of Medical Information Act"

1. In June of 1978 the Office of Management and Budget requested this Agency's views on subject proposed legislation (copy of draft is Attachment A). Subsequently the Office of Legislative Counsel, in coordination with appropriate CIA components, forwarded a views letter (Attachment B) containing our comments on the proposed bill.

2. Section 1185 of the draft bill mandates that medical care facilities shall not disclose medical information on a former patient to other than the patient or his designee unless the individual has authorized the disclosure. As it was not then clear in the bill how one defined patient, CIA took the position that the bill was intended to protect American citizens and possibly permanent resident aliens. Recently, we have received a letter from Secretary of Health, Education and Welfare Joseph Califano. In an attachment to his letter, Mr. Califano makes clear that

"The draft bill would cover all medical information contained by Medicare and Medicaid medical care facilities, irrespective of the citizenship of the patient." (emphasis added)

3. In light of the foregoing, CIA's views have been requested anew. It is requested that addressees consider in detail what deleterious affect, if any, this proposed denial of access (without the individual's consent) would have on CIA operations or activities. In preparing your response, you may wish to consider or provide as appropriate to your office the following:

a. Scope, nature and quantity of CIA activity, if any, in this realm that would be affected and how.

b. Programs, if any, that would have to be discontinued due to the bill's requirement of the individual's consent prior to release of medical information.

c. Per a. and b. above, the importance and value of programs, if any.

d. Separate, if possible, whether programs and activities involve only Foreign Nationals, only U.S. citizens, or both. In the latter case, please specify numbers or percentages in each classification.

4. Please keep in mind that, due to the way in which the bill is drafted, it will be very difficult to secure an amendment that would adequately protect CIA activities unless our only interest in this realm lies in Foreign Nationals. If that be the case, it will be necessary to attempt to secure amendatory language limiting the bill's coverage to U.S. persons and permanent resident aliens. Such a course would almost necessarily involve the Secretary, Mr. Califano.

5. It is imperative that I receive your written responses not later than close of business 20 November 1978. If you have questions or are in need of assistance, please feel free to telephone me at extension 6126.

STAT

Attachments:
As stated

Distribution:

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SUMMARY OF DRAFT BILL

Materials covered by the draft bill

The draft bill would cover "medical information": materials relating to the health, examination, care, or treatment of an individual that are in a form enabling the individual to be identified.

Facilities subject to the draft bill

The draft bill would apply to hospitals, skilled nursing facilities, and intermediate care facilities participating in the Medicare or Medicaid programs. The Secretary of Health, Education, and Welfare could also, by regulation, apply some or all of the provisions of the draft bill to other Medicare or Medicaid medical care facilities (such as clinical laboratories). The draft bill would not apply to federal facilities; they are subject to the Freedom of Information Act and to the Privacy Act of 1974.

Access by an individual to his own medical information

An individual (or a person designated by him, if the individual preferred) would have the right to inspect without charge, and be provided a copy of, any medical information that a medical care facility maintained concerning the individual. The Secretary could provide that, in certain circumstances in which harm might result, the individual himself would not inspect the medical information, but instead would be permitted to designate an appropriate representative to examine the materials.

Correction of medical information

If an individual requested a medical care facility to correct medical information concerning the individual, the facility would be required either to make the correction or to explain why it would not make the correction. If the facility did not make the correction, it would have to file with the medical information the individual's request for the correction and his reasons for requesting the correction. The correction (or the individual's request) would have to be included in future disclosures of the medical information, and be provided to anyone named by the individual to whom the information had been previously disclosed.

Notification concerning unauthorized disclosures

Medical care facilities would be required to provide advance written notification of the disclosures of medical information that could be made without an individual's consent, and would have to state the procedure, if any, by which an individual could learn of each kind of disclosure.

Limitation of disclosure to properly identified persons and to purpose for which needed

A disclosure of medical information could be made only to properly identified persons and, as a general rule, only to the extent needed to accomplish the purpose for which the disclosure was made.

Conditions for disclosure of medical information

The draft bill would prohibit medical care institutions from disclosing medical information, except for certain specified kinds of disclosure (see below), or unless an individual had signed an appropriate authorization for the disclosure of medical information concerning him.

Authorization for disclosure of medical information

An individual, in order to permit disclosure of medical information concerning him, would have to sign an authorization that was dated, made clear that the facility was among those authorized to disclose information about him, was specific as to the information to be disclosed, stated to whom the information could be disclosed, specified the purposes for which the information could be used, and specified the expiration date or event of the authorization. An individual could revoke his authorization at any time. The institution would have to keep on file as part of the medical information a copy of the individual's authorization.

Disclosure without an individual's consent

A medical care institution could disclose medical information without an individual's consent under the following circumstances:

1. to employees of or other persons responsible to the facility, to the extent needed to carry out their duties,
2. to health professionals assisting in caring for the individual,

3. in compelling circumstances affecting the health or safety of the individual or another person, but the facility would have to keep on file as part of the medical information a notation of the disclosure, and would have to inform the individual if his health or safety were involved,
4. for use in a biomedical, epidemiologic, or health services research project, or a health statistics project, if--
 - A. the disclosure did not violate any limitations established when the information was obtained,
 - B. the importance of the project and the disclosure were sufficiently great,
 - C. the head of the project provided adequate assurances that the information would be protected and that there would be a program to remove or destroy materials identifying the individual (unless there were good health, research, or statistics reasons not to), and
 - D. the head of the project provided assurances that further use or disclosure of the information would not be permitted, except for other research or health statistics purposes or under certain other specified circumstances,
5. to properly identified persons who stated they needed the information for a federal, state, or local government audit or evaluation purpose, to carry out the Maternal and Child Health, Professional Standards Review Organizations, Medicare, or Medicaid programs, or to investigate questionable activities under those programs, if the institution made a notation of the disclosure and had a procedure by which the individual could learn of the disclosure,
6. for a non-governmental audit or evaluation purpose, if adequate assurances were provided that the information would be protected, that there would be a program to remove or destroy materials identifying the individual, and that further use or disclosure would not be permitted except under

certain specified circumstances, and if the institution made a notation of the disclosure and had a procedure by which the individual could learn of the disclosure,

7. pursuant to a law authorizing disclosure to a public health authority, but the facility would have to keep on file as part of the medical information a notation of the disclosure,
8. to a law enforcement authority, pursuant to a law that requires specific types of information to be reported, but the facility would have to keep on file with the medical information a notation of the disclosure, and inform the individual of the disclosure,
9. when the information revealed only the presence of the individual at the institution or the provision of services to him, his location, or his general condition, but only if the individual had not objected to the disclosure, and only if the information were not of a kind determined by the Secretary to reveal specific information about the individual's condition, or
10. in response to a summons or subpoena.

Obtaining medical information through deception

Persons who, under false pretenses, requested or obtained medical information from a medical care facility would be subject to a fine of not more than \$10,000 and imprisonment for not more than one year.

Enforcement

Individuals could bring suit in federal or state court against medical care institutions that violated the provisions of the draft bill (and against persons who requested or obtained medical information under false pretenses), and could obtain \$1,000 in liquidated damages, reasonable attorney's fees, and other appropriate relief. A medical care institution could permit an institutional review board (meeting requirements established by the Secretary) to determine whether requests for disclosure for research or statistics purposes were permissible. In these circumstances an individual could bring suit only against the parent institution of the board, and could prevail only if the board had acted in an arbitrary or capricious manner.

Medical care facilities not in substantial compliance with the requirements of the draft bill would be subject to removal from the Medicare and Medicaid programs.

Disclosure of surveys of compliance

Surveys of compliance conducted by the federal government would be subject to the Freedom of Information Act and the Privacy Act of 1974. The draft bill would require surveys of compliance conducted by contractors on behalf of the federal government to be made public (except for any materials enabling individual patients to be identified).

Effect on state laws

The draft bill would override state laws only to the extent they were inconsistent with the provisions of the draft bill.

Minors, incompetent individuals, and individuals suffering from health conditions

The bill would provide for appropriate persons to act on behalf of minors (except in those circumstances in which the Secretary determined it was in the interest of a minor to act on his own behalf), incompetent individuals, and individuals not able to act effectively because of a health condition.

Effective date

The draft bill would take effect 180 days after enactment.

A B I L L

To protect the privacy of medical information maintained by medical care facilities, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That

SHORT TITLE

Section 1. This Act may be cited as the "Privacy of Medical Information Act".

PRIVACY OF MEDICAL INFORMATION

Sec. 2. Title XI of the Social Security Act is amended--

(1) by striking out in the heading "AND PROFESSIONAL STANDARDS REVIEW" and inserting instead ", PROFESSIONAL STANDARDS REVIEW, AND PRIVACY OF MEDICAL INFORMATION", and

(2) by adding after part B the following new part:

"PART C--PRIVACY OF MEDICAL INFORMATION

"ACCESS TO AN INDIVIDUAL'S OWN MEDICAL INFORMATION

"Sec. 1181. (a) A medical care facility shall (except as provided in subsection (b)), if requested by an individual, provide, at the choice of the individual, (1) the individual, (2) the individual and another person (designated by the individual) who accompanies him, or (3) a person designated by the individual, with an opportunity to inspect, and with a copy of, any medical information that the facility maintains concerning the individual. The facility may

not impose a charge for permitting such an inspection, and may not impose more than a reasonable charge (in any event no greater than the charge imposed on third persons) for providing such a copy.

"(b) A medical care facility shall provide an appropriate person (as defined by the Secretary) designated by the individual with an opportunity to inspect, and with a copy of, medical information that the facility maintains concerning the individual, in circumstances in which the Secretary determines that the application of the requirements of subsection (a) would be likely to be sufficiently harmful to the individual or to another person so as to outweigh the desirability of applying those requirements.

"CORRECTION OF MEDICAL INFORMATION

"Sec. 1182. If an individual requests that a medical care facility correct medical information that the facility maintains concerning the individual, the facility shall, within a reasonable period of time not to exceed three months, either--

"(1) make the correction requested, or

"(2)(A) inform the individual of its refusal to do so, the reasons for the refusal, and of the procedures, if any, for further review of the refusal, and

"(B) permit the individual to file with the facility a concise statement setting forth any correction requested, but not made, by the facility, and the reasons for requesting that correction. The facility shall, in any subsequent disclosure of medical information in which a correction was requested, include any correction made, and any statement filed as provided under clause (2)(B). The facility shall provide any person, specifically designated by the individual, to whom that medical information was previously disclosed with a copy of any correction made, and of any statement filed as provided under clause (2)(B).

"NOTIFICATION CONCERNING DISCLOSURE WITHOUT AN
INDIVIDUAL'S AUTHORIZATION

"Sec. 1183. A medical care facility shall notify an individual in writing of the disclosures that may be made of medical information concerning an individual without the authorization of the individual and of the procedure, if any, by which the individual can learn of each kind of disclosure. The facility shall provide that notification--

"(1) when the facility first maintains any medical information concerning an individual,

"(2) when the facility first provides services to an individual at least one year after it last provided services to the individual, and

"(3) when the facility first provides services to an individual after the effective date of the Act enacting this part.

"LIMITATION OF DISCLOSURE TO PROPERLY IDENTIFIED PERSONS AND TO PURPOSE FOR WHICH NEEDED

"Sec. 1184. A medical care facility may disclose medical information only to properly identified persons, and (except for disclosures under section 1185(b)(5)) only to the extent needed to accomplish the purpose for which the disclosure is made.

"CONDITIONS FOR DISCLOSURE OF MEDICAL INFORMATION

"Sec. 1185. (a) A medical care facility shall not disclose medical information that it maintains concerning an individual, except as provided in subsection (b), unless the individual has authorized the disclosure as provided in subsection (c) and the facility has complied with subsection (d).

"(b) The provision of subsection (a) prohibiting disclosure of medical information concerning an individual shall not apply to a disclosure by a medical care facility--

"(1) to a person employed by or responsible to the facility, to the extent that the person needs the information to carry out his duties.

"(2) to a health professional who is consulted by the facility, in connection with health services provided to the individual.

"(3) in compelling circumstances affecting the health or safety of the individual or another person, if--

"(A) a notation of such disclosure (and to whom the information was disclosed) is made part of the medical information that the facility maintains concerning the individual, and

"(B) when the circumstances affect the health or safety of the individual, the individual is notified of the disclosure (and to whom the information was disclosed),

"(4) for use in a biomedical, epidemiologic, or health services research project, or a health statistics project, if--

"(A) the disclosure does not violate any limitations placed upon the use or disclosure of the information at the time the information was obtained,

"(B) the importance of the project and the disclosure is sufficiently great to warrant the disclosure,

"(C) the person conducting the project provides adequate assurances that unauthorized disclosure of the information will be prevented, and that there will be a program to remove or destroy materials enabling the individual to be

identified, unless the person conducting the project presents an adequate justification of a research, statistics, or health nature for retaining those materials, and

"(D) the person conducting the project provides adequate assurances that further use or disclosure of the information will not be made, except --

"(i) for disclosure to a person employed by or responsible to the person conducting the project, to the extent needed to carry out the project,

"(ii) in compelling circumstances affecting the health or safety of the individual or another person,

"(iii) for use in another biomedical, epidemiologic, or health services research project, or a health statistics project, under the same limitations applicable under this part to its use in the original project,

"(iv) for disclosure to properly identified persons who state they need the information for a federal, State, or local government audit or evaluation purpose in relation to the project,

"(v) for an audit or evaluation purpose in relation to the project other than a federal, State, or local government audit or evaluation purpose, or

"(vi) pursuant to an administrative or judicial summons or subpoena,

"(5) to properly identified persons who state they need the information--

"(A) for a federal, State, or local government audit or evaluation purpose, or

"(B) to carry out a program under title V, part B of this title, title XVIII, or title XIX, or to conduct an investigation concerning fraud, abuse, or waste under those programs, if a notation of such disclosure (and to whom the information was disclosed) is made and there is a procedure by which the individual can learn of the disclosure,

"(6) for an audit or evaluation purpose other than a federal, State, or local government audit or evaluation purpose, if--

"(A) the person to whom the information is to be disclosed provides adequate assurances that unauthorized disclosure of the information will be prevented, and that there will be a program to remove or destroy materials enabling the individual to be identified,

"(B) the person to whom the information is to be disclosed provides adequate assurances that further use or disclosure of the information will not be made, except--

"(i) for disclosure to persons carrying out the audit or evaluation purpose,

"(ii) for disclosure to the person for whom the audit or evaluation is being conducted, or

"(iii) when required by federal or State law, and

"(C) a notation of such disclosure (and to whom the information was disclosed) is made and there is a procedure by which the individual can learn of the disclosure,

"(7) pursuant to a federal or State law authorizing disclosure to a public health authority, if a notation of such disclosure (and to whom the information was disclosed) is made part of the medical information that the facility maintains concerning the individual,

"(8) to a law enforcement authority, pursuant to federal or State law that requires specific types of information to be reported, if--

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"(A) a notation of such disclosure (and to whom the information was disclosed) is made part of the medical information that the facility maintains concerning the individual, and

"(B) the individual is notified of the disclosure (and to whom the information was disclosed),

"(9) revealing only the presence of the individual at the facility or the provision of services to the individual, his location, or his general condition, if--

"(A) the individual has not objected to the disclosure, and

"(B) the information is not of a kind determined by the Secretary to reveal specific information about the individual's condition, or

"(10) pursuant to an administrative or judicial summons or subpoena.

"(c) An authorization for disclosure referred to in subsection (a) shall--

"(1) be in writing,

"(2) be dated,

"(3) be signed by the individual,

(4) make clear that the individual is among those either specifically named or generically designated by the individual as authorized to disclose information concerning the individual,

"(5) be specific as to the nature of the information authorized to be disclosed,

"(6) state specifically named or generically designated persons to whom the information may be disclosed,

"(7) be specific as to the purposes for which the disclosed information may be used, and

"(8) specifically state the expiration date or event of the authorization.

An authorization may be revoked in whole or in part at any time.

"(d) A medical facility which discloses medical information that it maintains concerning an individual pursuant to an authorization specified in subsection (c) shall make a copy of the authorization part of the medical information that it maintains concerning the individual.

"COMPLIANCE WITH THIS PART AS A CONDITION FOR PARTICIPATION
IN MEDICARE AND MEDICAID

"Sec. 1186. (a) A medical care facility may not continue to participate in the program under title XVIII unless the facility provides adequate assurances, and evidence from time to time, to the Secretary of its substantial compliance with the requirements of sections 1181 through 1185.

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"(b) A medical care facility may not continue to participate in a program under title XIX unless the facility provides adequate assurances, and evidence from time to time, to the appropriate State agency of its substantial compliance with the requirements of sections 1181 through 1185.

"DUTY OF INSTITUTIONAL REVIEW BOARD

"Sec. 1187. If an institutional review board undertakes to determine whether medical information maintained by a medical care facility may be disclosed because the disclosure would not violate section 1184 and would meet the requirements of section 1185(b)(4), it shall make that determination in a manner which is neither arbitrary nor capricious.

"OBTAINING MEDICAL INFORMATION THROUGH DECEPTION

"Sec. 1188. Any person who, under false pretenses, requests or obtains medical information concerning an individual from a medical care facility shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than \$10,000 or imprisoned for not more than one year, or both.

"CIVIL SUITS

"Sec. 1189. (a) Any person aggrieved by--

"(1) a violation by a medical care facility of any provision of sections 1181 through 1185,

"(2) a violation by an institutional review board of section 1187, or

"(3) the commission of acts which constitute a crime under section 1188, may bring a civil action in any appropriate United States district court, without regard to the amount in controversy, or in any other court of competent jurisdiction, against, in case of a violation under clause (1), the medical care facility, in case of a violation under clause (2), the parent entity of the institutional review board, or, in case of the commission of acts under clause (3), the person who committed the acts, and may obtain appropriate relief, including \$1,000 in liquidated damages, compensatory damages, reasonable attorney's fees and reimbursement for other reasonable litigation costs, and, where circumstances warrant, punitive damages and equitable relief.

"(b) It shall be a defense to an action brought against a medical care facility under subsection (a)(1) for a violation of section 1184 or 1185(a) that an institutional review board determined that the disclosure involved violated neither section 1184, nor section 1185(a) because of the applicability of section 1185(b)(4).

"DISCLOSURE OF SURVEYS OF COMPLIANCE

"Sec. 1190. (a) Any limitation in section 1106 concerning the disclosure of information shall not apply to information (except for materials in medical information

enabling an individual to be identified) contained in surveys of compliance with the provisions of this part conducted by or for the Secretary.

"(b) If the Secretary enters into a contract for conducting a survey of compliance with the provisions of this part, the contract shall require the contractor to make available to the Secretary and for public inspection all information (except for materials in medical information enabling an individual to be identified) obtained for, and any reports resulting from, that survey.

"EFFECT ON STATE LAWS

"Sec. 1191. This part shall override State laws only to the extent that those laws are inconsistent with the provisions of this part.

"DEFINITIONS AND RELATED MATTERS

"Sec. 1192. For purposes of this part--

"(1) 'medical information' concerning an individual means materials that--

"(A)(i) contain information relating to the health, examination, care, or treatment of the individual, or (ii) are to be added to such materials under provisions of this part, and

"(B) are in a form enabling the individual to be identified,

"(2) 'medical care facility'--

"(A) means an entity, other than a federal entity, that (i) is a hospital, skilled nursing facility, or intermediate care facility, as defined for purposes of title XVIII or XIX, and (ii) has been approved by the Secretary for participation in the program under title XVIII, or certified by a State agency for participation in a program under title XIX, and

"(B) means, but only with respect to those provisions that the Secretary makes applicable to an entity by regulation, an entity, other than a federal entity, that (i) is an entity (other than a hospital, skilled nursing facility, or intermediate care facility, as defined for purposes of title XVIII or XIX) for which approval by the Secretary is required for participation in or coverage under the program under title XVIII, or for which certification by a State agency is required for participation in a program under title XIX, and (ii) has been approved by the Secretary for participation in or coverage under the program under title XVIII, or certified by a State agency for participation in a program under title XIX,

"(3) the rights of, and obligations with respect to, an individual, shall be exercised by, and discharged through, respectively--

"(A) in the case of an individual under 18 years of age, a parent or guardian of the individual, except (i) in those circumstances in which the Secretary determines that it is in the interest of the individual to exercise his own rights and to have obligations with respect to him discharged through him, or (ii) as otherwise provided in subclause (B), and

"(B) in the case of an incompetent or deceased individual (or of an incompetent parent or guardian under subclause (A)), or of an individual (or of a parent or guardian under subclause (A)) suffering from a health condition which the Secretary determines prevents the individual (or parent or guardian) from acting effectively on the individual's behalf, such other person as determined by the Secretary.

"(4) a requirement to provide a notification or other matter to a person shall be satisfied if the notification or matter is sent to the last known address of the person.

"(5) 'arbitrary' and 'capricious' have the meanings of those terms under 5 U.S.C. 706(2)(A); and

"(6) 'institutional review board' means--

"(A) such a board under section 474(a) of the Public Health Service Act, or

"(B) a similar board which meets such requirements as the Secretary may specify."

EFFECTIVE DATE

Sec. 3. This Act is effective 180 days after its enactment.

THE DIRECTOR OF CENTRAL INTELLIGENCE

OLC 10-4205/A

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Office of Legislative Counsel

JUN 1978

Mr. James M. Frey
Assistant Director for
Legislative Reference
Office of Management and Budget
Washington, D.C. 20503

Dear Mr. Frey:

I am writing in response to your request for the views of this Agency on HEW's draft legislation, entitled the "Privacy of Medical Information Act."

In our view, the draft bill does not apply to the Central Intelligence Agency. The term "medical care facility" (section 1192, page 13), in establishing those organizations to which the bill would apply, excludes a "federal entity"; the CIA would be such a facility. Moreover, the types of health services which CIA provides its employees would not qualify under the draft legislation's definition of "medical care facility."

Although the draft bill does not define the classes of persons who fall within the term "patient," we presume the intent of HEW is to have the protective provisions of this bill available only to citizens of the United States and possibly permanent resident aliens. In order to be absolutely clear on this point, we urge that such definition be included in the body of the draft or that it be clearly explained in the legislative history. As this Agency's interests lie in the realm of foreign intelligence and by extension to certain foreign persons in the United States, we take no issue with the draft as written, assuming, as stated above, the bill does not provide coverage to foreign persons, who may, from time to time, seek medical care in the United States.

We appreciate the opportunity to comment on this proposed legislation, and will be happy to provide any additional information concerning our interests therewith. We would appreciate being kept advised of the progress of this proposal, particularly as regards the issues discussed in this letter.

Sincerely,

SIGNED

Acting Legislative Counsel

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